



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of : Frank Forrest Humbles

Serial No.: 10/698,205

Examiner: Mayo-Pinnock, Tara L.
Art Unit: 3671

Filing Date: 31 October 2003

Invention: SURGICAL ARM POSITIONING PAD

DECLARATION

Now comes the undersigned and declares and says as follows:

1. My name is Frank Forrest Humbles. I am a physician licensed to practice in the State of South Carolina and practice the medical specialty of anesthesiology. A copy of my curriculum vitae is attached and incorporated by reference herein.

2. As part of my duties as an anesthesiologist, I am involved in positioning patients who are undergoing anesthesia in an operation. It is necessary to appropriately position a patient on an operating room table. An operation may last a few minutes or many hours and during that period of time, the patient must be kept comfortable. Patients arms must be positioned to avoid injury to the arms and its neurovascular bundles, from stretching, pressure, or other risk that accompanies a fully anesthetized patient who cannot move or give information to the operation room personnel regarding extremities, especially arms.

3. As part of these duties I recognized there was a need for a better method for an arm positioning and protection device than was available in the marketplace. The hard sleds or soft wraps such as sheets which are commonly used simply do not provide protection both for the patient and for the operating room personnel. Consequently, I devised and invented the surgical arm positioning pad which is the subject of my application. This invention provides the following advantages which have been long been recognized, but not met by any previous device on the market.

a. It provides a simple patient positioning device which can be manufactured at a reasonable price and which may be used a single time without the need for concern of compromising the sterile operative field.



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Now comes the undersign who declares and says as follows:

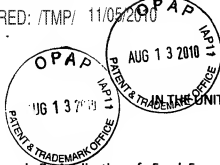
1. My name is Thomas Holt and I am a resident of Conway, SC.

2. That I am a Certified Registered Nurse Anesthetist who is licensed to practice this profession in the State of South Carolina. A copy of my curriculum vitae is attached and incorporated by reference herein.

3. As part of practicing my profession I have become familiar with the surgical arm positioning pad invented by Dr. Frank F. Humbles and sold under the trade name "Lap Wrap".

4. That the surgical arm positioning pad referenced above represents an advance of prior art devices such as hard sleds or using sheets or soft wraps. This device meets important needs for positioning and protection of patient's extremities, especially arms, in that it does the following: positions the patients arm in a comfortable and secure manner next to the torso thus allowing the surgeon and assistants to be close to the operating field for procedures on the torso and head and neck. The wrap safely pads the pressure points on the arms, yet still allows easy access to the upper extremities for IV lines, arterial lines, blood pressure cuffs and other monitors.

5. I think the surgical arm positioning pad, "LapWrap" has met a long felt, but previously unmet need for an arm positioning device to be used in an operating room. I have been in practice for 26 years and this is the safest and easiest to use arm positioning device, and to my knowledge is the only one of its kind I have ever seen in an operating room.



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Now comes the undersign who declares and says as follows:

1. My name is Paul L. Sasser and I am a resident of Conway, South Carolina
2. That I am a general/vascular surgeon who is licensed to practice this profession in the State of South Carolina. A copy of my curriculum vitae is attached and incorporated by reference herein.
3. As part of practicing my profession I have become familiar with the surgical arm positioning pad invented by Dr. Frank F. Humbles and sold under the trade name "Lap Wrap".
4. That the surgical arm positioning pad referenced above represents an advance of prior art devices such as hard sleds or using sheets or soft wraps. This device meets important needs for positioning and protection of patient's extremities, especially arms, in that it does the following: positions the patient's arm in a comfortable and secure manner next to the torso thus allowing the surgeon and assistants to be close to the operating field for procedures on the torso and head and neck. The wrap is quick and easy to apply, protects the patient's arms from neurovascular injury but also allows for easy access to the arms for nerve monitoring or vascular access.
5. I think the surgical arm positioning pad, "LapWrap" has met a long felt, but previously unmet need for an arm positioning device to be used in an operating room. The "Lap Wrap" is on my needs card for all my head and neck surgery as well as my laparoscopic surgeries.

EX 171515 D



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Now comes the undersign who declares and says as follows:

1. My name is William L. Mills and I am a resident of Conway, South Carolina.
2. That I am an Orthopedic spine surgeon who is licensed to practice this profession in the State of South Carolina. A copy of my curriculum vitae is attached and incorporated by reference herein.
3. As part of practicing my profession I have become familiar with the surgical arm positioning pad invented by Dr. Frank F. Humbles and sold under the trade name "LapWrap".
4. That the surgical arm positioning pad referenced above represents an advance of prior art devices such as hard sleds or using sheets or soft wraps. This device meets important needs for positioning and protection of patient's extremities, especially arms, in that it does the following: positions the patients arm in a comfortable and secure manner next to the torso thus allowing the surgeon and assistants to be close to the operating field for procedures on the anterior cervical spine. The wrap is quick and easy to apply, protects the patient's arms from neurovascular injury but also allows for easy access to the arms for spinal cord nerve monitoring during my anterior cervical spine surgery.
5. I think the surgical arm positioning pad, "LapWrap" has met a long felt, but previously unmet need for an arm protective/positioning device to be used in an operating room. I have used the Lap wrap for years now and have recommended it to many other spine surgeons as well.